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The Effect of Footbath on Sleep Quality of the Elderly: A Blinded Randomized Clinical Trial

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ABSTRACT

Introduction: The progressive increase in the elderly population of developing countries has drawn attention to their health. Sleep Pattern and quality can affect life quality in old people. We need more documents about footbath (a non-invasive method). The purpose of this research was to examine footbath on sleep quality of the elderly. ***Methods:*** This study is a blinded, randomized, clinical trial on 46 old men that had health documents in health center, 2013. Participants in the research were divided into two groups. One group had footbath (experimental group) and another group did not have footbath (control group). The experimental group participants were asked to put their feet in warm water (41-42 ºC) for 20 minutes before sleeping for 6 weeks. The co-researcher completed the Pittsburgh Sleep Quality Index (PSQI) before and after the intervention by individual interview. Data were analyzed by SPSS software.
Results: The comparison of changes in sleep quality score the old men showed the sleep duration and total sleep quality has significantly improved in the experimental group.
Conclusion: According to the study results, the maximum effect of footbath was on sleep latency and sleep duration disturbances. In this study, the researchers had limited access to the elderly in Tabriz; therefore, it is recommended that future research be conducted in a higher number of health centers.

Introduction

Sleep is a physiological mechanism of regaining energy and recovering from fatigue, and it has an important role in people`s health.[1,2]

The age pyramid of world population is changing. The world's elderly population (above 60 years of age) was 10% of the total population in 2000, 11.0% in 2010, and it is estimated that it will be 16.6% in 2030.[3]

This demographic change is sensed more in developing countries.[4] The elderly population (above 60 years of age) in Iran was 7.2% in 2006, and 8.2% in 2011.[5,6] The increase in the elderly population in developing countries has drawn more attention to this aged group's health.[7] According to the study by Cotroneo et al., sleep disturbances are the third most common problem after headache and digestive disorders, and it is a cause of reference to doctors among old people.[3] Sleep onset or its renewal are common disorders among the elderly. Eser et al., found that 60.9% of elderly people have sleeping difficulties.[8] In Iran 67% of elderly people have sleep disturbances.[9] Different studies have shown that sleep disorders may even be in association with accidents, falling down, reduction in recognition behavior and self-attentiveness, poor health condition, poor life quality, and mortality. In addition, poor sleep quality is

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related to stress and nap during day.[10-12]

The effect of many non-pharmacological methods on the sleep quality in the elderly has been investigated. For example, the studies of Chan et al., about the effects of music, Kirisoglu and Guilleminault about effects of light, de Castro Toledo Guimaraes et al., about effects of exercise, and Reza et al., study about effects of massage.[11,13-15] Footbath is a nursing intervention and non-pharmacological method that can help the elderly to relax and have a good feeling, but few studies have examined it in this aspect.[16]

Skin temperature rhythm and core body temperature have a functional relationship with sleep and wakefulness cycle. Rectal temperature increases after waking up and its peak is in the afternoon. There is a negative relationship between core body temperature and sleep tendency. When core body temperature decreases, sleep onset is more possible. Decreasing core body temperature before and during sleep is associated with dilation in peripheral blood vessels, and it may drive heat from core body to peripheral blood vessels. Therefore, a footbath with warm water can increase blood and peripheral body temperature without increasing or decreasing core body temperature and it can increase sleep quality and ease sleep onset.[17,18]

The base of previous studies was polysomnography and brain symptoms evaluation. These studies were costly and could not evaluate subjective sleep symptoms. Furthermore, participants in these studies were both men and women. Therefore, this study was done with the PSQI and samples were of one sex. These two methods are totally different and facilitate the similarity of groups and control of confounder variables. The aim of this study was the evaluation of the effect of footbath, as an easy and safe non-pharmacological intervention, on improvement of sleep quality of elderly men.

Materials and methods

This research is a blinded randomized clinical trial in which the co-researcher collected demographic data. The research ethics committee in Tabriz university of medical sciences approved the study. The participants were separated into two groups; intervention group and control group.

The inclusion criteria were having partial ability in doing daily activities, no night shift job, and possessing health in all dimensions of sense, temperature, audition, vision, and mental health according to health documents in the health center.

The exclusion criteria were enuresis, start using complementary and alternative medicine except sleep drugs (which was included in questions on the sleep quality index), having diabetes for more than 10 years, and sense disorders.

Sampling was done from April until June 2013 in Tabriz, Iran. For sample size detection, a pilot study was done on 8 elderly men in Monempour health center. By considering $\alpha = 0.05$ and Power = 0.9 and the mean and standard deviation for difference 3.25 (2.98) in the footbath group and 0.25 (1.7) in the control group, sample size has been estimated to be 20 persons for each group. Considering the possibility of participant dropouts 25 persons were determined for each group and in total 50 aged persons were entered into the study. Selection and allocation of subjects for intervention and control groups was done with random method by random numbers chart. Clinical trial performance manner is shown in figure 1.

The researcher called the participants and invited them to the study. In the first session, the researcher explained the aim of study to the participants. After gaining their approval and consent forms, the co-researcher completed PSQI for the two groups with individual interview and pen and paper method. The intervention group was taught the footbath method. For example, they were taught to evaluate water temperature with a thermometer. The researcher supervised their

work. This training continued until all participants could do footbath the right way. For doing footbath, the participants were asked to put their ankles into 41-42°C water for 20 minutes, one hour before their usual time of sleeping, every night for 6 weeks with a special thermometer provided by the researcher and plastic container marked at 10 cm depth. The data collection tool has two parts; the first part consists of demographic data and second part consists of PSQI, which measures quality and patterns of sleep in adults. This questionnaire was made by Buysse et al., (1989) for evaluation of sleep quality and diagnosis of sleep disturbance.[19] The questionnaire consists of 18 questions in 7 domains of subjective sleep quality, sleep latency, sleep duration, sleep efficiency, sleep disturbances, use of sleep medications, and day time dysfunction. The score of each question is between 0-3 and the maximum score of each part is 3. Total mean score of

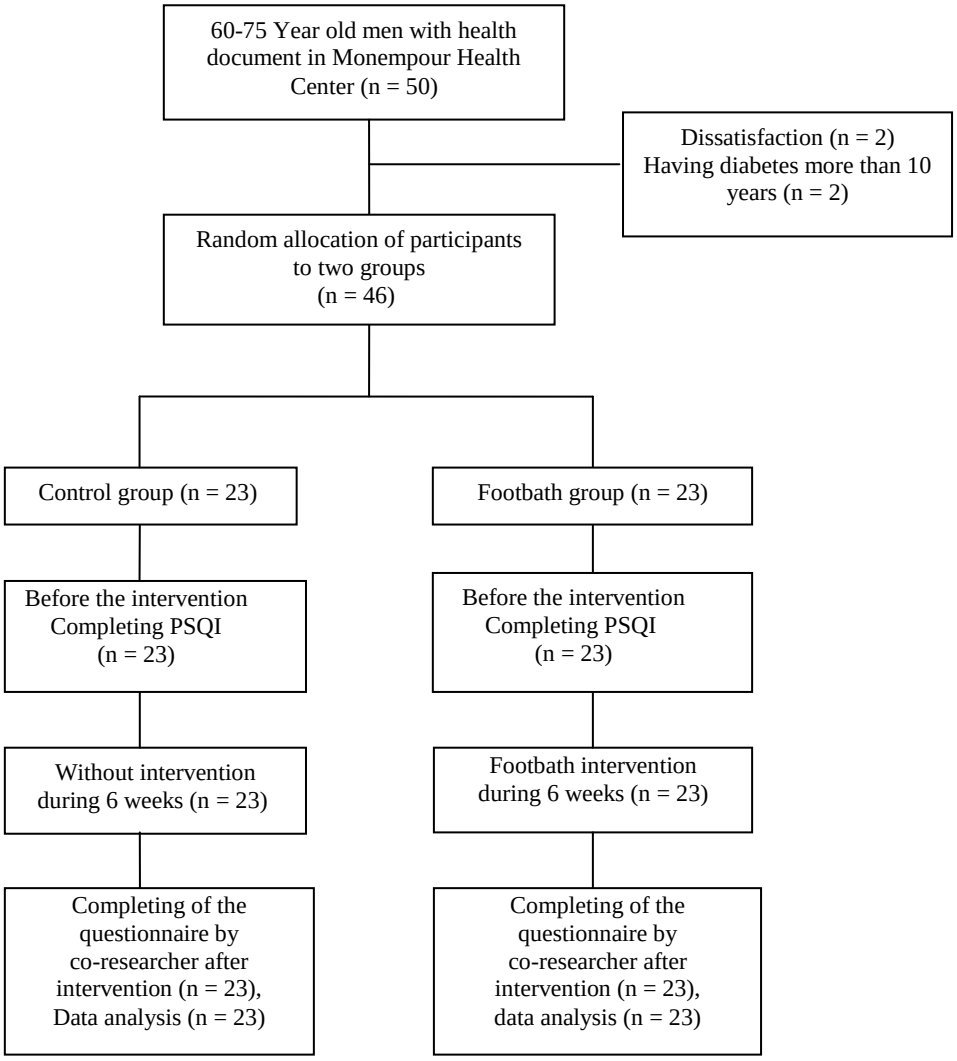

Figure 1. Sampling and intervention

these seven components makes the total score of the instrument and ranges between 0-21. Scores higher than 5 show poor sleep quality.

For reliability of this questionnaire, Persian text of PSQI with the aim of the research was given to 10 professors of Tabriz University of

Medical Sciences; the translation of the seventh part of the questionnaire was corrected. In the study by Agargun et al., the PSQI validity with Cronbach's alpha was 0.8, and its reliability with retest was 0.93-0.98.[20] The reliability of this tool, in the study by Hosseinabadi et al., in Iran, with Cronbach's alpha was 0.88.[15] In the present research, the reliability of this tool with 12 male participants with Cronbach's alpha was 0.8. Data was analyzed with SPSS for Windows (version 13; SPSS Inc., Chicago, IL., USA).

Sleep quality score was determined by use of mean descriptive index, standard deviation, frequency, and frequency percentage. First, normality of data was investigated using the Kolmogorov-Smirnov test (K-S). Then, sleep quality score was compared before and after the intervention with the Wilcoxon test. Moreover, for comparison of the two groups the Mann-Whitney statistical test was used and for similarity background variables of the two groups the Mann-Whitney and chi-square tests were used. The significance level for these tests was considered to be $p < 0.05$.

Results

This study was done by 46 participants. The mean age and standard deviation of participants were 67.26 (4.05). The majority of participants were literate. Demographic data is shown in table 1. There is no statically significant difference between the two groups of participants in age, literacy, and income (Table 1). All participants were married and lived with their wives. None of them had extra light and noise problems in their bedroom and none of them used medical pillows and mattresses.

In order to evaluate sleep quality the seven domains of the PSQI and total score of this questionnaire were analyzed. Mean and standard deviation of sleep quality in participants decreased after footbath in comparison with before the intervention. The comparison of questionnaire components before and after footbath showed that the intervention was useful except for sleep efficiency and using sleep medications. However, the score of the seven domains in this questionnaire showed no statically significant difference in sleep quality in the control group (Table 2).

The comparison of changes in sleep quality scores of the two groups before and after the intervention showed that the

Table 1. Demographic data of participants

Variables	experimental group (n = 23) N (%)	Control group (n = 23) N (%)	Statistical indicators
Education			
Illiterate	3 (13)	0 (0)	$\chi^2 = 20.95$
Elementary	2 (8.7)	3 (13)	df = 6
Guidance school	1 (4.3)	3 (13)	P = 0.37
Diploma	9 (39.1)	8 (34.8)	
Post diploma	5 (21.7)	2 (8.7)	
Bachelor degree	3 (13)	3 (13)	
Master's degree	0 (0)	4 (17.4)	
Economic status			
Equal income and expense	11 (.847)	11 (47.8)	$\chi^2 = 20.13$
Income more than expense	0 (0)	1 (4.3)	df = 2
Income less than expense	12 (52.2)	11 (47.8)	P = 0.88
			$U^{\dagger} = 0.50$
Age*	67.49 (4.28)	66.82 (3.84)	Z = -0.66
			P = 0.50

* Data are given as mean (SD), † Mann-Whitney

Table 2. Mean and standard deviation of sleep quality score before and after the intervention

Components of questionnaire	Footbath group (n = 23)				Control group (n = 23)			
	Before intervention Mean (SD)	After intervention Mean (SD)	95% CI for difference	P Wilcoxon	Before Mean (SD)	After Mean (SD)	95% CI for difference	P Wilcoxon
Subjective sleep quality	1 (0.67)	0.60 (0.58)	0.00, 0.06	0.01	0.91 (0.51)	0.73 (0.54)	0.13, 0.38	0.10
Sleep latency	1.39 (1.07)	0.47 (0.89)	0.00, 0.06	0.001	0.95 (1.06)	0.69 (1.06)	0.11, 0.36	0.10
Sleep duration	1.52 (1.03)	0.78 (0.90)	0.00, 0.06	0.004	0.82 (0.98)	0.91 (0.99)	0.63, 0.88	0.71
Sleep efficiency	1.04 (1.33)	0.60 (0.98)	0.03, 0.22	0.09	0.56 (1.03)	0.39 (0.78)	0.35, 0.64	0.49
Sleep disturbances	1.17 (0.38)	0.78 (0.51)	0.00, 0.06	0.007	1.04 (0.20)	0.91 (0.41)	0.21, 0.48	0.18
Use of sleep medication	1.13 (1.42)	0.73 (1.28)	0.06, 0.28	0.09	1.13 (1.45)	0.73 (1.28)	0.21, 0.48	0.73
Day Time dysfunction	0.34 (0.48)	0.13 (0.34)	0.00, 0.10	0.02	0.30 (0.63)	0.26 (0.54)	0.93, 1.00	0.14
Total score	7.30 (0.68)	4.13 (3.57)	0.00, 0.06	0.001	4.69 (0.51)	5.69 (3.08)	0.08, 0.31	0.14

components of sleep latency and sleep duration, and total statues of sleep quality improved in the footbath group (Table 2). Mann-Whitney test for total score of sleep quality before and after the intervention showed no statistically significant difference (Table 3). 69.6% of the elderly in the footbath group and 56.5% in control group were poor sleeper; there was no statistically significant difference between the two groups before the intervention (P = 0.54).

After the intervention, sleep disturbances decreased to 39.1% in the footbath group and 47.8% in control group. Although there is no statically significant difference between the two groups, there is a clinically significant difference between them (Table 4).

Discussion

The results of the present study showed that after the intervention, sleep quality of participants increased. Although comparison of sleep quality in some domains of this

Table 3. Comparison of changes in sleep quality score of two groups before and after the intervention in the two groups

Components of questionnaire	Footbath group (n = 23)	Control group (n = 23)	Statistical indicators
	Mean rank	Mean rank	
Subjective sleep quality	25.52	21.48	U^* = 218.00 Z = -1.22 p = 0.22
Sleep latency	28.09	18.91	U^* = 159.00 Z = -2.49 p = 0.01
Sleep duration	28.63	18.37	U^* = 146.50 Z = -2.84 p = 0.004
Sleep efficiency	25.02	21.98	U^* = 229.50 Z = -0.90 p = 0.36
Sleep disturbances	25.91	21.09	U^* = 209.00 Z = -1.55 p = 0.12
Use of sleep medication	23.43	23.58	U^* = 263.50 Z = -0.04 p = 0.96
Day time dysfunction	25.67	21.33	U^* = 214.50 Z = -0. 47 p = 0.14
Total score	29.48	17.58	U^* = 127.00 Z = -3.05 p = 0.02

* Mann-Whitney

Table 4. Comparison of sleep Pattern in footbath and control groups

Groups	Before		After	
	Poor Sleeper N (%)	Good sleeper N (%)	Poor Sleeper N (%)	Good sleeper N (%)
Footbath group (n = 23)	16 (69.60)	7 (30.40)	9 (39.10)	14 (60.90)
Control group (n = 23)	13 (56.50)	10 (43.50)	11 (47.80)	12 (52.2)
Statistical indicators	$\chi^2 = 0.84$, df = 1 p = 0.54		$\chi^2 = 0.35$, df = 1 p = 0.76	

questionnaire, such as sleep efficiency and use of sleep medications, showed no significant difference before and after the intervention, footbath intervention caused a significant difference in the five other domains (Table 2). According to the results, the maximum effect of footbath was on sleep latency and sleep duration (Table 2). Comparison of score variability of sleep quality between the two groups showed that maximum changes occurred in sleep latency and sleep duration, and changes in total score of sleep quality was statically significant (Table 3). Based on table 4 persons in the footbath group showed recovery in terms of sleep disturbance at the end of the intervention; this is clinically significant in comparison with 2 persons in the control group. Moreover, it showed that footbath causes an increase in sleep quality of the elderly. The results show that sleep disturbance decreased from 69.6% to 39.1% in the footbath group and it decreased from 56.5% to 47.8% in the control group. This decreasing was more visible in the footbath group compared to the control group (Table 4).

The results of this study are in accordance with the results of the study by Yang et al., in the study by Yang et al., footbath in warm water increased sleep quality. There was a statistically significant difference in sleep quality between the intervention and control groups ($p < 0.05$). This study had 21 participants with 0.7 power, and the sleep quality of participants was evaluated with the Verran and Snyder-Halpern Sleep scale (VSH).[21]

The results of the study by Sung and Tochihara, showed that footbath caused better sleep onset.[22]

The results of the study by Liao et al., showed that footbath before sleep increases feet and rectal temperature. This study is not in accordance with the study by Sung and Tochihara. The study of Liao et al., showed that footbath does not have a significant effect on sleep.[18] This is not in agreement with our study. Intervention methods and tools in the study by Liao et al. are the cause of this difference. The study by Liao et al., was done with 25 participants in two groups by using polysomnography; however, our study was done with 46 participants by using PSQI. The intervention in the study of Liao et al. consisted of 40 ± 0.5°C water, 20 minutes to 50 minutes before sleeping and 20 cm above the ankle.

The study by Saeki showed that footbath does not have any effect on pulse rate and respiratory rate, but it decreases blood flow significantly. Parasympathetic system activity increased significantly with footbath.[16] This findings supports the recent study results.

In this study, the researcher was limited to few health centers in Tabriz, Iran, thus it is recommended that this study be performed with a larger sample size and in more health centers.

Conclusion

Overall findings of the current study confirmed the hypothesis. The results of this study show that footbath is effective in sleep quality of the elderly, decreases sleep latency, and increases efficient sleep duration. Because the rate of sleep problems is high in the elderly, we can use footbath as a non-pharmacological, easy and safe method to manage this problem. As this method can be performed for the elderly by themselves or other people, it can be recommended in health programs for them.

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Ethical issues

None to be declared.

Conflict of interest

The authors declare no conflict of interest in this study.

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